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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Per Marin

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Baker & Botts
30 Rockefeller Plaza
New York, NY 10112-4498

EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,613

Applicant(s)

MARIN ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 18-20 is/are rejected.
- 7) ☒ Claim(s) 16, 17 and 21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

CLAIMS 13-21 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed December 28, 2001 have been received and entered into the application. Accordingly, claims 1-12 have been canceled, claims 13-21 have been added, the specification at page 1 and the Title have been amended and the Abstract has been added. Also, as reflected by the attached, completed copy of form PTO-1449 (2 pages), the cited references have been considered by the Examiner.

Claim Objections

Claim 21 is objected to because of the following informalities:

In order to be grammatically correct, this claim should include a form of the verb "administer". Appropriate correction is required.

Claims 16 and 17 are also objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 21 recites "the daily dosage", (line 1) however claim 18, from which claim 21 depends, does not explicitly provide antecedent basis for this expression.

Also in claim 21 "a subject" (line 2) is broader in scope than the host of claim 18, i.e., "a mammalian subject". This point may be overcome by changing "a subject" to ---the subject---.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

I Claims 13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Giles (U.S. Patent No. 4,603,141, Applicants' cit. No. 12) and Applicants' acknowledgment in the present specification at page 6, lines 8-11 of the first full paragraph.

Applicants are advised that the acknowledgment at page 6 is being relied upon as provided for by MPEP 2131.01 (C), i.e., to show that a characteristic not disclosed in the reference is inherent.

Giles teaches the administration of clonidine or salts thereof for the treatment of chronic congestive heart failure (note present claims 13 and 14) and for increasing exercise tolerance in individuals so afflicted (note present claim 19). Applicants have acknowledged in the present specification at page 6, lines 8-11 of the first full paragraph that clonidine was known to be a cortisol antagonist.

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II Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Scheurer et al. (Am J Physiol 1997 Jun; 272 (6 Pt 2): R2017-2024, Applicants' cit. No. 6) and Applicants' acknowledgment in the present specification at page 6, lines 12-16 of the first full paragraph.

Applicants are advised that the acknowledgment at page 6 is being relied upon as provided for by MPEP 2131.01 (C), i.e., to show that a characteristic not disclosed in the reference is inherent.

Scheurer et al. teach the administration of mifepristone reduces the infarct size, i.e., a cardiac pathology of claim 13, in corticosterone-treated rats, i.e., a mammal of claim 13. Further, Applicants have acknowledged in the present specification at page 6, lines 12-16 of the first full paragraph that mifepristone was known to be a cortisol antagonist.

III Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Beale (U.S. Patent No. 5,756,469, cited by the Examiner).

Beale teaches a composition which may comprise a cortisol blocker, i.e., a cortisol antagonist, and pyruvate, i.e., an additional drug.

The recitations in the present claim which related to how the composition is administered or how the composition is to be used does not impart patentable moment to the claimed composition because such recitations do not provide for any physical or otherwise material limitation not present in the prior art composition.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giles, as relied upon above.

The difference between the above and applicants' claimed subject matter lies in that Giles only highlights exercise tolerance as a symptom associated with congestive heart failure while in present claims 19-20 other symptoms are listed.

However, to the skilled artisan, the claimed subject matter would have been obvious because Giles teaches the treatment of congestive heart failure and logic would dictate that if the disease itself is treated in a host, then too would the symptoms associated with said disease.

Reference not Relied Upon


Schatzberg et al. (U.S. Patent No. 6,362,173), which is cited by the Examiner on the attached form PTO-892 and not relied upon, is included to show the general state of the art.

None of the claims are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is 703-308-4652. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Raymond J. Henley III
Primary Examiner
Art Unit 1614

Rjh
September 20, 2003